

Dana Hannon of Wyckoff, New Jersey was a 29-year old, newly-engaged member of the New York City Engine Company #28, who responded to the reports of a plane crash at the north and south towers of the World Trade Center.

Paul Laszczynski of Paramus was a Port Authority police officer who was honored for his action during the first attack on the World Trade Center. He and a colleague carried a wheelchair-bound victim down 77 floors to safety after the bombing in 1993.

Joe Navas of Paramus was a 44-year old Port Authority police officer. In his hometown of Paramus he volunteered as a Little League Coach for his two boys. His wife and family had to learn about his earlier heroic exploits by reading it in the Bergen Record.

The example set by Joe Navas is not unique. Our fire departments and emergency services are the first on the scene to fires, motor vehicle accidents, natural disasters, hazardous waste spills, and, yes, even terrorist attacks.

And they never draw attention to themselves. In their minds, they are "just doing their jobs . . ."

That Tuesday, their work and their courage brought them into the building lobbies as people flooded out into the streets. These men and women ran up the stairs while instructing people to immediately get down those same stairs and outside. They ran to help as others ran to safety. Their efforts will never be forgotten, especially by those who were saved.

Someday we may hear the story of the lives these men and women saved or the comfort they provided. But for now, we can be proud: proud of the job they were doing, proud of the heroism they showed that day, and proud of the courage they have always shown. New Jersey lost a tragic number of officers and emergency workers in lower Manhattan that day. As we wait for stories about New Jersey's finest, we will continue to share the memories of their everyday heroism and spirit.

Mr. Speaker, the men and women that we honor today died on their own terms—fighting selflessly against those who hate all that our country stands for. Our tenacious American spirit will prevail. As President Reagan said in his first Inaugural Address, "we must realize that no arsenal, or no weapon in the arsenals of the world, is so formidable as the will and moral courage of free men and women. It is a weapon our adversaries in today's world do not have. It is a weapon that we as Americans do have."

On behalf of Congress, let us now recognize the men and women who served us in our most horrific hours by awarding these heroes Congressional Gold Medals. I strongly urge my colleagues to support this legislation.

This action today is another way of saying God Bless America. Truly we are "one Nation under God."

Ms. SCHAKOWSKY. Mr. Speaker, I rise in support of H.R. 3054, a bill to award the Congressional Gold Medal to the heroes of September 11. I hope that this small token of appreciation will symbolize America's appreciation for the endless bravery that was shown on that day.

There are some, for whom there is no sacrifice too great when the call to duty sounds. There are some, in a world wrapped in a shroud of self-promotion, who see beyond the "me", the "my", the "mine" and the "I". There

are some that so regard their brothers and sisters that they disregard their own safety, their own well being, and even their own lives, to lend a hand. There are some, which in a split second make a decision to forget themselves and do what it takes to save others; they are heroes.

For heroes, there is no room to think or to rationalize. It is never practical to endanger one's existence in the hope of promoting the survival of others, but they do. It goes beyond what is logical. The hero possesses an innate and instinctive ability to respond to extreme situations with others in mind. By nature, the hero defies the basic human impulse for self-preservation. The hero is selfless.

On September 11, many Americans heeded the call to action. On a beautiful morning, ordinary people awakened to start the day, to go about their normal routines with smiles, frowns, traffic, and cups of coffee. The Pentagon was still an impenetrable fortress and the skyline of New York was still intact; the morning proceeded as usual. In the moments to follow, shocked and horrified, firefighters, police officers, servicemen and women, and everyday people sprang into situations that were simply incomprehensible; they fought to save lives. They saved lives and returned to save more, and in an instant, the courageous fire that burned in their hearts was extinguished.

Above the mayhem, Flight 93 swam the skies to reach the West Coast. Aboard this flight the passengers eagerly awaited landing, waiting to meet their loved ones miles away. Nonetheless, with angry shouts the silence was broken and the passengers realized that terror's arm had reached yet another flight. The terrorists made their move and fought to carry out this horrible act. They were headed to Washington, DC to destroy the very symbols that shine as beacons for freedom throughout the world. The terrorists were trained and prepared to destroy lives and break the spirit of America. However, they were never trained to defeat the spirit of heroism.

The passengers of Flight 93, after talking to their courageous and heroic family members and learning of the attacks, decided that there would be no more death and destruction. They decided that America had suffered enough for one morning. They decided that they would trade their lives to save hundreds, maybe thousands more, quite possibly my own. For them, heroism was not the goal. They did not seek a grand prize or recognition. They sought only to prevent the destruction that was sure to come absent their intervention.

For heroes, there is no reward other than the satisfaction of knowing that their sacrifice may allow the life of others to continue. Since September 11, America has received so many lessons in heroism. We have been schooled in selflessness and courage. We have learned what it means to sacrifice. We can only honor and thank them for these lessons and for the lives that they saved, and the lives they gave.

The Congressional Gold Medal is the nation's highest civilian award. The medal recognizes outstanding achievements and unusual acts of valor and courage. Be it over a lifetime or in one instance, it recognizes that its recipients have—in their own way—changed the world for the better. The heroes of 9–11 have shown a courage that is rare to modern times. They fought the hatred and the malice of that ter-

rible day with love, compassion, courage and selflessness. And they changed the world.

It is difficult to find good in such a tragic event. However, we can look to the many men and women who worked tirelessly and who died courageously to save life, and know that even in the face of death and terror, the good in humanity prevails. The Congressional Gold Medal is but a small token, but I hope it will symbolize the immeasurable thanks that we pay to these heroes. I urge my colleagues to support this bill.

Mr. KING. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. SIMPSON). The question is on the motion offered by the gentleman from New York (Mr. KING) that the House suspend the rules and pass the bill, H.R. 3054, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds of those present have voted in the affirmative.

Mrs. MALONEY of New York. Mr. Speaker, I object to the vote on the ground that a quorum is not present and make the point of order that a quorum is not present.

The SPEAKER pro tempore. Pursuant to clause 8, rule XX and the Chair's prior announcement, further proceedings on this motion will be postponed.

The point of no quorum is considered withdrawn.

ENERGY POLICY ACT OF 1992 AMENDMENTS

Mr. SHIMKUS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3343) to amend title X of the Energy Policy Act of 1992, and for other purposes, as amended.

The Clerk read as follows:

H.R. 3343

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. REAUTHORIZATION OF THORIUM REIMBURSEMENT.

(a) PAYMENTS TO LICENSEES.—Section 1001(b)(2)(C) of the Energy Policy Act of 1992 (42 U.S.C. 2296a(b)(2)(C)) is amended—

(1) by striking "\$140,000,000" and inserting "\$365,000,000"; and

(2) by adding at the end the following: "Such payments shall not exceed the following amounts:

"(i) \$90,000,000 in fiscal year 2002.

"(ii) \$55,000,000 in fiscal year 2003.

"(iii) \$20,000,000 in fiscal year 2004.

"(iv) \$20,000,000 in fiscal year 2005.

"(v) \$20,000,000 in fiscal year 2006.

"(vi) \$20,000,000 in fiscal year 2007.

Any amounts authorized to be paid in a fiscal year under this subparagraph that are not paid in that fiscal year may be paid in subsequent fiscal years."

(b) AUTHORIZATION.—Section 1003(a) of such Act (42 U.S.C. 2296a–2(a)) is amended by striking "\$490,000,000" and inserting "\$715,000,000".

(c) DEPOSITS.—Section 1802(a) of the Atomic Energy Act of 1954 (42 U.S.C. 2297g–1(a)) is amended by striking "\$488,333,333" and inserting "\$518,233,333" and by inserting after "inflation" the phrase "beginning on the date of the enactment of the Energy Policy Act of 1992".

(d) PORTSMOUTH.—(1) Chapter 19 of the Atomic Energy Act of 1954 (42 U.S.C. 2015 and following) is amended by inserting the following after section 241:

“SEC. 242. COLD STANDBY.

“The Secretary is authorized to expend such funds as may be necessary for the purposes of maintaining enrichment capability at the Portsmouth, Ohio, facility.”.

(2) The table of contents for such chapter is amended by inserting the following new item after the item relating to section 241:

“Sec. 242. Cold standby.”.

SEC. 2. COMPTROLLER GENERAL AUDIT.

The Comptroller General shall conduct an audit on the Uranium Enrichment Decontamination and Decommissioning Fund established under section 1801 of the Atomic Energy Act of 1954 (42 U.S.C. 2297g). Not later than March 1, 2003, the Comptroller General shall transmit to the Congress a report on the results of the audit. Such report shall assess whether the Fund as currently authorized will be of sufficient size and duration for carrying out decontamination and decommissioning and remedial action activities anticipated to be paid for from the fund, and shall include recommendations for minimizing increases in such activities. In conducting the audit, the Comptroller General shall specifically address whether the deposits collected under sections 1802(c) and 1802(d) of the Atomic Energy Act of 1954 (42 U.S.C. 2297g-1(c) and 2297g-1(d)) are sufficient to—

(1) pay for decontamination and decommissioning activities pursuant to section 1803(b) of the Atomic Energy Act of 1954 (42 U.S.C. 2297g-2(b));

(2) pay for the remedial action costs pursuant to section 1803(c) of such Act (42 U.S.C. 2297g-2(c)); and

(3) pay for the remedial action costs pursuant to section 1001(b)(2)(C) and (D) of the Energy Policy Act of 1992 (42 U.S.C. 2296a(b)(2)(C) and (D)).

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Illinois (Mr. SHIMKUS) and the gentleman from Virginia (Mr. BOUCHER) each will control 20 minutes.

The Chair recognizes the gentleman from Illinois (Mr. SHIMKUS).

GENERAL LEAVE

Mr. SHIMKUS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks on this legislation and to insert extraneous material on the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Illinois?

There was no objection.

Mr. SHIMKUS. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, first let me pay tribute to our former colleague on the Committee on Energy and Commerce, Speaker HASTERT, who has put much time into this legislation. His support and help is greatly appreciated.

Mr. Speaker, this legislation will authorize the Federal Government, pursuant to title X of the Energy Policy Act of 1992, to continue to pay its share of decommissioning and remediation costs for a thorium site in West Chicago, Illinois. The thorium facility was utilized extensively by the government during the development of our country's nuclear defense program, including the Manhattan Project.

Under title X of EPACT, the Department of Energy determined that the

government was responsible for 55.2 percent of West Chicago cleanup costs, reflecting the portion of tailings attributable to government contracts. Remediation activities in West Chicago involve the decommissioning of the original factory site as well as remediation of certain vicinity properties. Cleanup of the original factory site is expected to conclude in 2004.

Congress has been fiscally responsible in adjusting the thorium payment limitation to match actual remediation activities. EPACT initially set this authorization ceiling at \$40 million in 1992, which was a reasonable approximation of known estimated costs at that time. In 1996, as additional costs were incurred, this cap was raised to \$65 million. Again in 1998 as cleanup activities proceeded, the cap was raised to its current level of \$140 million. We have taken great care in the past to adjust this level only in conjunction with demonstrated needs.

The \$225 million adjustment in this bill will further increase the thorium cap consistent with identified costs at the West Chicago site. It is also important to note that this increased authorization will continue to be subject to the annual appropriations process. What we are seeking to do is provide authority for the Federal Government to meet its obligations.

Today, there is already a shortfall in authorized funding for the Federal share of West Chicago cleanup cost of more than \$60 million. The \$225 million reauthorization requested by this bill will allow the government to begin meeting its obligation to reimburse those costs, which will be after verification and auditing by the government. Equally important, this legislation will provide the authorization necessary to fund the government's share of all West Chicago decommissioning and remediation costs.

During the committee markup, an amendment was agreed to that attempted to address issues that were raised by both Democratic and Republican members. The amendment included language directing a Comptroller General audit of the D&D fund to see if the fund is capable of meeting the expected cleanup costs of all the facilities that receive, or will receive, funding from this program. All Members of this body are supportive of cleaning up contaminated facilities. This audit will give us a better idea of just exactly what we are up against.

Mr. Speaker, I reserve the balance of my time.

Mr. BOUCHER. Mr. Speaker, I yield myself such time as I may consume.

(Mr. BOUCHER asked and was given permission to revise and extend his remarks.)

Mr. BOUCHER. Mr. Speaker, I rise in support of H.R. 3343, legislation amending title X of the Energy Policy Act of 1992, and chapter 28 of the Atomic Energy Act to increase the authorization ceiling on the Federal share of cleanup costs at a thorium site in West Chicago, Illinois.

Section 1001 of the Energy Policy Act establishes the responsibility of licensees for bearing the costs of decontamination, decommissioning, reclamation and other remedial action at active uranium and thorium sites where by-product material has been produced. However, the section also requires the Secretary of Energy to reimburse annually a licensee for that portion of the remedial cost that the Secretary has determined is attributable to by-product material generated as the result of sales to the Federal Government. In the case of the West Chicago site, DOE has determined that 55.2 percent of the remedial cost is attributable to government contracts.

The money for the Federal Government's share of the cleanup comes from the Uranium Enrichment Decontamination and Decommissioning Fund established in Chapter 28 of the Atomic Energy Act from revenues collected from the utility industry and deposited in the fund by the Secretary of Energy. This fund also is used to pay the cleanup costs at 13 uranium mining sites and three uranium enrichment facilities. Therein lies the potential problem associated with raising the ceiling on the thorium cleanup: Competition between 17 cleanup sites for the finite, and probably insufficient, amount of money that will be deposited in the decontamination and decommissioning fund.

Fortunately, as reported by the Committee on Energy and Commerce, this legislation avoids that competition and hopefully leaves everyone at least a bit better off than they otherwise would be under current law. This compromise is the result of the dedication and hard work of a number of Members and staff on both sides of the aisle. In particular, I want to express commendation to our full committee ranking member the gentleman from Michigan (Mr. DINGELL) and to the chairman of the full Committee on Energy and Commerce the gentleman from Louisiana (Mr. TAUZIN) for crafting this compromise language in a truly bipartisan manner. I also want to commend the outstanding efforts of the gentleman from Ohio (Mr. STRICKLAND), the gentleman from Kentucky (Mr. WHITFIELD) and the bill's sponsor the gentleman from Illinois (Mr. SHIMKUS) for their fine work in arriving at the product that we are considering today. As always, I want to thank the chairman of the Subcommittee on Energy and Air Quality, the gentleman from Texas (Mr. BARTON) for his outstanding assistance in processing this measure.

I will take just a moment, Mr. Speaker, to point out the five main provisions of the compromise embodied in the bill now before the House.

First, it accomplishes the original objective of the bill, to increase the total thorium reimbursement authorization from \$140 million to \$365 million and increase the total authorization for appropriations for title X programs from \$490 million to \$715 million.

Secondly, it stipulates annual amounts to be authorized for thorium activities in each of the fiscal years 2002 through 2007. The amounts for each year are sufficient to cover the likely receipts from thorium cleanup and structured in such a way that aims to prevent competition within the cleanups at the Ohio, Kentucky and Tennessee facilities.

Third, the compromise language increases by \$37.5 million the total amount currently required by law to be deposited in the uranium enrichment decontamination and decommissioning fund each year. This provision increases the size of the fund by at least the additional amount of money that will be authorized for thorium cleanup in order to hold harmless the cleanups at the Ohio, Kentucky and Tennessee facilities and at the 13 uranium mine sites.

Fourth, the substitute authorizes the Secretary of Energy to expend funds to keep the Portsmouth, Ohio uranium enrichment facility in cold standby mode. Maintaining the Portsmouth facility in this mode is wise because it allows the facility to be used again if needed to protect the continuity of domestic supply or to meet DOE's contract demands.

□ 1530

I want to be sure to note that this authorization neither expands nor contracts the current universe of activities that can be paid for with monies from the Uranium Enrichment Decontamination and Decommissioning Fund. In fact, the cold-standby authorization was drafted to amend chapter 19 of the Atomic Energy Act, rather than chapter 28, in order to help make clear that Congress expects the Department to use money other than that deposited in the Decontamination Fund for the very worthwhile purpose of keeping the Portsmouth facility in cold-standby mode.

Finally, Mr. Speaker, H.R. 3343 requires the General Accounting Office to audit the Uranium Enrichment Decontamination and Decommissioning Fund and the cleanups authorized to receive appropriations from the fund and report to us by March 1, 2003. The audit has two general purposes: first, to ensure that the fund is and will be sufficient to cover the costs of all the activities authorized, and, if not, to make legislative recommendations to maintain the adequacy of the fund; secondly, to look at the current and likely costs of cleanup activities at each site in order to project the total needs of the fund, identify the factors resulting in increased cleanup costs, and to identify potential sources of savings.

Mr. Speaker, I support this legislation. I encourage the Members to approve it.

I want to commend all of the Members who worked to craft this compromise language, which is meritorious and deserves the support of the House.

Mr. Speaker, I reserve the balance of my time.

Mr. SHIMKUS. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I already mentioned the gentleman from Illinois (Speaker HASTERT) and his work, but I would also be remiss if I did not mention the staff on both our side and the minority side for their great work in working out the difficulties and differences. Because of their efforts, we are able to be here on the suspension calendar and pass this bill.

I also want to mention my colleagues who were personally engaged in this. One is going to speak on the floor in a minute, the gentleman from Ohio (Mr. STRICKLAND), who is a fervent supporter of many issues, and this is one of them. I appreciate his help and friendship.

I also want to recognize the gentleman from Kentucky (Mr. WHITFIELD), who also had some vested interests involved in this, the gentleman from New Mexico (Mrs. WILSON), who was very engaged, and the gentleman from Oklahoma (Mr. LARGENT), who all took an active role in working with us to craft legislation that would be acceptable to the whole body.

This is a good product, and I urge its passage.

Mr. Speaker, I reserve the balance of my time.

Mr. BOUCHER. Mr. Speaker, I am pleased to yield 4 minutes to the gentleman from Ohio (Mr. STRICKLAND), a valuable member of the Committee on Energy and Commerce.

(Mr. STRICKLAND asked and was given permission to revise and extend his remarks.)

Mr. STRICKLAND. Mr. Speaker, first I would like to thank the chairman and the ranking member of the Committee on Energy and Commerce and especially my friend, the gentleman from Illinois (Mr. SHIMKUS), the sponsor of this bill. I would like to thank the gentleman from Illinois (Speaker HASTERT) and his staff for their work on the bill.

I am pleased that the substitute offered in committee helps to ensure that cleanup activities at the three uranium enrichment sites in our country do not suffer a setback as we increase funding available for the thorium processing site under title X of the Energy Policy Act of 1992. There is no doubt that all of these sites need to be cleaned up and these activities do not come cheaply.

It is important that we clean up the thorium processing site in West Chicago, Illinois; and I completely understand the Speaker's desire to ensure Federal funds are available to do so. However, because the funds to clean up the thorium site come from the Uranium Decommissioning and Decontamination Fund, it is important to me and my friends from Kentucky and Tennessee that the reimbursement for cleanup of the Illinois site does not shift funds from the cleanup activities at the three uranium enrichment sites. It is also important that the burden for

cleaning up the thorium site does not fall on nuclear-powered ratepayers.

I know the intent of this bill is to address both of those issues by holding harmless the uranium enrichment sites' cleanup schedule and protecting our nuclear ratepayers from shouldering the additional costs of cleaning up the site in West Chicago, Illinois.

I would like to say a special thanks to the Speaker, to the gentleman from Louisiana (Chairman TAUZIN), to the ranking member, the gentleman from Michigan (Mr. DINGELL) and to the gentleman from Illinois (Mr. SHIMKUS) for their help to include a provision in the bill that authorizes the Department of Energy to carry out necessary activities at the Portsmouth, Ohio, enrichment plant so that we can maintain our country's uranium enrichment capability.

I have talked about our domestic uranium enrichment industry on numerous occasions before this Chamber, and I am pleased to see this bill includes a cold-standby provision for the Portsmouth site.

I would also like to make clear that this cold-standby authority for the Department is not intended to compete for funds from the Department's cleanup Uranium Enrichment D&D Fund. Instead, this important energy security objective should be met by expending funds from the USEC Privatization Fund or from other discretionary funds.

Mr. Speaker, I support this bill; and I urge my colleagues to support it as well.

Mr. SHIMKUS. Mr. Speaker, I yield myself 1 minute.

Mr. Speaker, I want to follow up on my colleagues' thank-you's to thank the chairman, the gentleman from Louisiana (Chairman TAUZIN); the ranking member, the gentleman from Michigan (Mr. DINGELL); the subcommittee chairman, the gentleman from Texas (Mr. BARTON); and, of course, managing on the minority side, the gentleman from Virginia (Mr. BOUCHER), for their great work in helping us move this bill expeditiously.

Mr. DINGELL. Mr. Speaker, I rise in strong support of H.R. 3343.

H.R. 3343 would amend Title X of the Energy Policy Act of 1992 (EPACT) and Chapter 28 of the Atomic Energy Act to increase the authorization ceiling on the Federal share of cleanup costs at a thorium site in West Chicago, Illinois.

The Committee on Energy and Commerce reported this bill unanimously last week. The reason for that was the development of compromise language that avoids competition for money between cleanup sites and leaves everyone at least a little bit better off than they would otherwise be under current law.

As reported, the bill not only increases the total thorium reimbursement authorization so that Federal contribution to the cleanup effort can continue, but it accomplishes that goal without robbing Peter to pay Paul. By establishing annual amounts to be authorized for thorium activities in each of the fiscal years 2002–2007, it ensures there will be adequate

funds remaining for cleanups at the Ohio, Kentucky, and Tennessee facilities. The bill also increase the sizes of the Uranium Enrichment Decontamination and Decommissioning Fund in order to hold harmless the cleanups at the other facilities and mine sites, without raising the fees currently assessed on utility ratepayers. In addition the bill requires the General Accounting Office to audit the Fund to ensure it is, and will be, sufficient to cover the costs of all the activities authorized and to look at the current and likely costs of the cleanup activity at the various sites.

Last but not least, the bill contains language authored by the gentleman from Ohio, Representative STRICKLAND, that provides specific authorization for the Secretary of Energy to expend funds to keep the Portsmouth, Ohio, uranium enrichment facility in "cold-standby" mode. I believe this to be wise, for it allows the Secretary to use the facility again if needed to protect the continuity of domestic supply or to meet the contract demands of the Department.

I want to again thank my good friend, Chairman TAUZIN, and commend all the Members who worked with us to craft this compromise language, including Representatives STRICKLAND and WHITFIELD, Chairman BARTON and Ranking Member BOUCHER, of course the sponsor of the bill, representative SHIMKUS. I also want to thank Speaker HASTERT, with whom I have worked many times on legislation to ensure the cleanup of thorium wastes, for his assistance in moving this bill forward with bipartisan support.

H.R. 3343 is good legislation and deserves the support of all Members.

Mr. BOUCHER. Mr. Speaker, I have no further requests for time. I urge support for this measure, and I yield back the balance of my time.

Mr. SHIMKUS. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. SIMPSON). The question is on the motion offered by the gentleman from Illinois (Mr. SHIMKUS) that the House suspend the rules and pass the bill, H.R. 3343, as amended.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

BEST PHARMACEUTICALS FOR CHILDREN ACT

Mr. TAUZIN. Mr. Speaker, I move to suspend the rules and pass the Senate bill (S. 1789) to amend the Federal Food, Drug, and Cosmetic Act to improve the safety and efficacy of pharmaceuticals for children.

The Clerk read as follows:

S. 1789

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Best Pharmaceuticals for Children Act".

SEC. 2. PEDIATRIC STUDIES OF ALREADY-MARKETED DRUGS.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) by striking subsection (b); and

(2) in subsection (c)—

(A) by inserting after "the Secretary" the following: "determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and"; and

(B) by striking "concerning a drug identified in the list described in subsection (b)".

SEC. 3. RESEARCH FUND FOR THE STUDY OF DRUGS.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended—

(1) by redesignating the second section 409C, relating to clinical research (42 U.S.C. 284k), as section 409G;

(2) by redesignating the second section 409D, relating to enhancement awards (42 U.S.C. 284l), as section 409H; and

(3) by adding at the end the following:

"SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

"(a) LIST OF DRUGS FOR WHICH PEDIATRIC STUDIES ARE NEEDED.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop, prioritize, and publish an annual list of approved drugs for which—

"(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j));

"(ii) there is a submitted application that could be approved under the criteria of section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j));

"(iii) there is no patent protection or market exclusivity protection under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or

"(iv) there is a referral for inclusion on the list under section 505A(d)(4)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(C)); and

"(B) in the case of a drug referred to in clause (i), (ii), or (iii) of subparagraph (A), additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

"(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary shall consider, for each drug on the list—

"(A) the availability of information concerning the safe and effective use of the drug in the pediatric population;

"(B) whether additional information is needed;

"(C) whether new pediatric studies concerning the drug may produce health benefits in the pediatric population; and

"(D) whether reformulation of the drug is necessary.

"(b) CONTRACTS FOR PEDIATRIC STUDIES.—The Secretary shall award contracts to entities that have the expertise to conduct pediatric clinical trials (including qualified universities, hospitals, laboratories, contract research organizations, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct pediatric studies concerning one or more drugs identified in the list described in subsection (a).

"(c) PROCESS FOR CONTRACTS AND LABELING CHANGES.—

"(1) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS LACKING EXCLUSIVITY.—The Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, may issue a written request (which shall include a

timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified in the list described in subsection (a)(1)(A) (except clause (iv)) to all holders of an approved application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act. Such a written request shall be made in a manner equivalent to the manner in which a written request is made under subsection (a) or (b) of section 505A of the Federal Food, Drug, and Cosmetic Act, including with respect to information provided on the pediatric studies to be conducted pursuant to the request.

"(2) REQUESTS FOR CONTRACT PROPOSALS.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under paragraph (1) within 30 days of the date on which a request was issued, or if a referral described in subsection (a)(1)(A)(iv) is made, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for contract proposals to conduct the pediatric studies described in the written request.

"(3) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for contract proposals under paragraph (2).

"(4) GUIDANCE.—Not later than 270 days after the date of enactment of this section, the Commissioner of Food and Drugs shall promulgate guidance to establish the process for the submission of responses to written requests under paragraph (1).

"(5) CONTRACTS.—A contract under this section may be awarded only if a proposal for the contract is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

"(6) REPORTING OF STUDIES.—

"(A) IN GENERAL.—On completion of a pediatric study in accordance with a contract awarded under this section, a report concerning the study shall be submitted to the Director of the National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study.

"(B) AVAILABILITY OF REPORTS.—Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(D))) and shall be assigned a docket number by the Commissioner of Food and Drugs. An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the written comments shall become part of the docket file with respect to each of the drugs.

"(C) ACTION BY COMMISSIONER.—The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (7).

"(7) REQUESTS FOR LABELING CHANGE.—During the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner of Food and Drugs shall—

"(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied;

"(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

"(C)(i) place in the public docket file a copy of the report and of any requested labeling changes; and